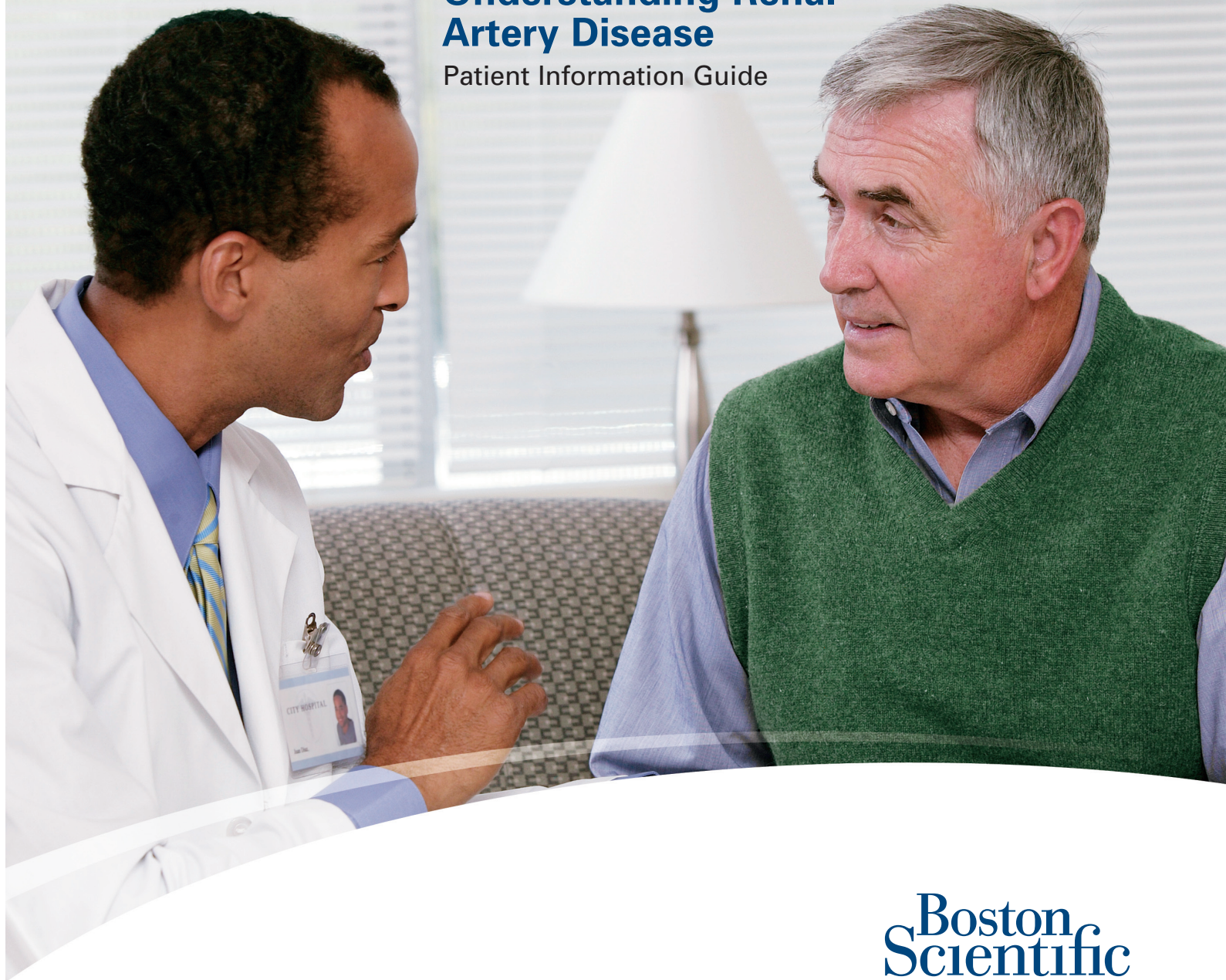


Understanding Renal Artery Disease

Patient Information Guide



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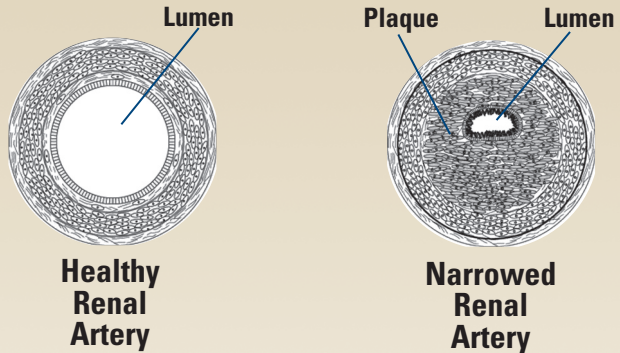
Treating renal artery disease

Your physician has recommended you have a renal artery stenting procedure. This guide explains what renal artery disease is and the various treatment options for it, including detailed information about the renal artery stenting procedure. You will learn about what you can expect before, during and after your stenting procedure. The glossary at the end of this guide defines medical terms related to renal artery stenting in easy-to-understand language.

Your physician may also recommend lifestyle changes to help reduce your risk factors for renal artery disease. See page 11 to learn about these risk factors and the steps you can take toward a healthier life.

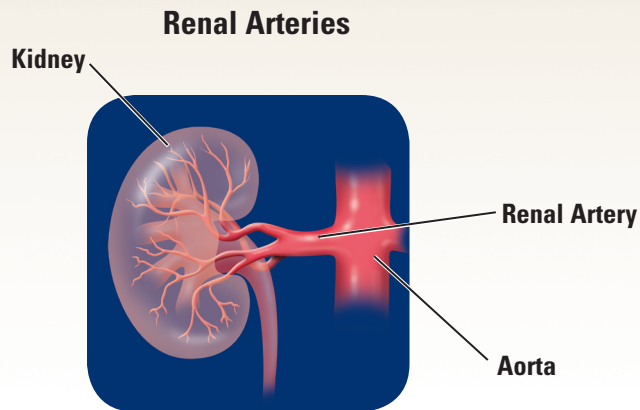
What is renal artery disease?

Renal artery disease is a condition caused by the narrowing of the arteries leading to one or both kidneys. This narrowing, or stenosis, is usually caused by a buildup of fatty and/or calcium deposits called plaque on the inside of the arteries. Over time, this plaque buildup, also called atherosclerosis or hardening of the arteries, can progress to a total blockage (occlusion) of the artery.



When the kidney doesn't receive enough blood because of a blockage in the artery, it sends a signal to the body to increase the blood pressure. This causes high blood pressure (hypertension) that can be very difficult to control. High blood pressure can increase strain on the heart by speeding the spread of atherosclerosis to other parts of the body, and it can also affect the kidney's ability to filter the blood and remove waste.

Your kidneys are located on either side of your spine, just below your rib cage. They filter waste materials out of your blood and help keep your blood pressure in the normal range. The arteries that carry blood to your kidneys are called renal arteries.



Renal artery disease treatment options

There are four different treatment options for renal artery disease. All of them focus on increasing blood flow to the kidneys. The type of treatment your physician recommends depends on the presence and severity of your symptoms.

1. Medical therapy

For patients with mild to moderate symptoms, physicians generally recommend medical therapy, which includes medication and regular exams. The physician may prescribe drugs that dilate and expand the arteries, to increase blood flow to the kidneys and control high blood pressure. Regular physical exams, including blood pressure checks and blood tests, can help determine if and when additional treatment is needed.

2. Surgery

For patients with severe high blood pressure or kidney failure, surgery may be needed. There are two types of surgery to treat renal artery disease. During a renal artery endarterectomy, the surgeon makes an incision in the abdomen to expose the renal artery. Then the plaque inside the artery is physically removed. Patients who have this procedure are usually in the hospital for about a week. The other type of surgery, called a renal artery bypass, is similar to an endarterectomy, except the surgeon uses a healthy vein from another part of your body to make a new path around the narrowed or blocked renal artery. This surgery also usually requires about a weeklong hospital stay.

3. Angioplasty

Angioplasty can be performed to treat vessel narrowing. A balloon catheter is advanced, using x-rays for guidance, to the area of the renal artery that is to be treated. The end of the catheter contains a small folded balloon. When the balloon is inflated, it pushes the plaque outward and stretches the artery wall to expand, in an attempt to improve blood flow. The balloon is deflated and removed after the angioplasty is performed. Angioplasty is less invasive than surgery, and the patient remains awake while the physician performs the procedure.

4. Renal artery stenting

During this minimally invasive procedure, a small, expandable wire mesh tube called a stent is placed into the renal artery, after balloon angioplasty has been performed, to keep it open.

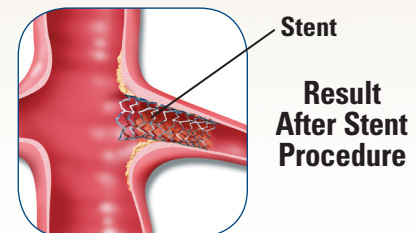
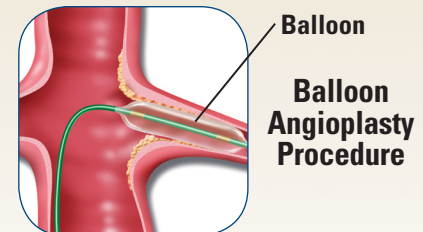
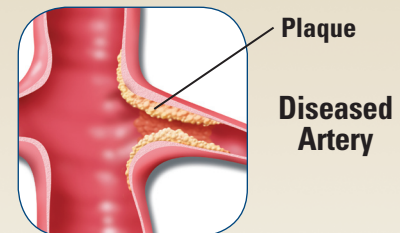
Here is what usually happens during a typical renal artery stenting procedure

1. A small puncture is made in your groin. A needle is used to gain access to the femoral artery, where a wire is then fed through the femoral artery and advanced into the aorta or main blood vessel of the body. A catheter is then introduced over the wire into your body, and the physician advances it to the narrowed section of your renal artery. All wire and catheter movement is done using x-rays for guidance.

2. The diseased artery first needs to be enlarged to make room for the stent. To do this, the physician places a small, deflated balloon over the wire and through the catheter to the blocked area of the renal artery. When the balloon is in the correct position, it is inflated. This pushes the plaque buildup aside and reopens the artery to restore blood flow.

3. The balloon is deflated and removed, and a small metal mesh tube called a stent is advanced into the same blocked area of the artery and expanded against the artery wall.

4. After the stent is implanted, the catheter and wire are removed and the puncture site in your groin is closed. The stent remains in place and is designed to help keep the artery open and prevent future narrowing of the renal artery.



Images courtesy of Boston Scientific.
Images are for illustration purposes
only, and are not necessarily to scale.

Before your procedure

Below is a typical checklist that your physician may require you to go through before your procedure.

- ☐ Tell your physician about any medications you are taking.

- ☐ Take all your prescription medications with you.

- ☐ Let your physician know about any allergies you may have, especially to contrast dye or iodine, to metals (cobalt, chromium, nickel, titanium or stainless steel) or to plastics (polyurethane).

- ☐ Tell your physician if you cannot take aspirin or blood thinning medicines, because these medications are usually prescribed before and after your procedure.

- ☐ Do not eat or drink anything after midnight on the night before your procedure.

- ☐ Follow the instructions you receive from your physician and nurses.

- ☐ Make sure you understand the possible risks and benefits of your renal stent procedure.

- ☐ Be aware that you may be given a sedative to relax you before starting your stent procedure. The sedative may make you sleepy.

During a typical renal stenting procedure

1. You will be taken into an angiographic suite or catheterization lab and moved onto an x-ray table. The procedure will be done through the femoral artery in your leg just above your thigh bone. To prepare for the incision, your groin area will be washed, shaved and covered with a sterile sheet.
2. You will be injected with a local anesthetic to numb the area where the guide catheter will be inserted. After the initial sting, you may feel a brief warm sensation as the medicine is injected.
3. Your physician will insert a needle into your femoral artery to introduce the guide catheter into your artery.
4. Your physician will inject contrast dye into the guide catheter. This helps the physician see the renal arteries on an x-ray monitor. You may feel warm or flushed for a short time.
5. Your physician will inflate the artery at the lesion site with a balloon catheter to open the artery.
6. Your physician will insert the stent, guide it to the lesion area and expand it to flatten the plaque against the artery wall in the diseased section of the artery.
7. Your physician may insert a balloon catheter into the stent to open it wider, then deflate the balloon and remove it. The stent will remain in place to keep the artery open.
8. Your physician will take out the balloon catheter and the guide catheter. The small entry site in your groin will be closed by applying pressure to the site or by using a vascular closure device.

After a typical renal stenting procedure

PRECAUTIONS

- You may feel sleepy from the sedative given to you, but this should wear off in time.
- You will be taken to an observation unit for monitoring by nurses and doctors.
- Your heart rate, blood pressure, neurological status and the entry site in your groin will be checked frequently.
- You will be asked to drink lots of fluids to flush the contrast dye out of your system. You will have to stay in bed for several hours, keeping your leg straight so the entry site in your groin can heal well.
- You may need to stay in the hospital for one or two days.
- You should alert your doctor or nurse if you experience any of these symptoms.
 - Severe dizziness, near blackout or fainting
 - Severe, unrelieved headache
 - Sudden blurriness or blindness in one eye or both eyes
 - Sudden weakness or clumsiness of a hand
 - Sudden weakness or paralysis of the face, arm or leg
 - Unexplained slurring of speech or difficulty with comprehension
 - Pain, bleeding or infection at the entry site in your groin

Your stent implant card

Your stent implant card (see right) notifies physicians, dentists and nurses that you have an Express® SD Renal Monorail® Premounted Stent System implanted in your renal artery. This card also identifies the physician who implanted your stent, the physician's contact information, the hospital where the procedure was performed, the date the stent was implanted, and the location where the stent was placed in your renal artery. Other important information such as the size of the stent and the date the stent was manufactured is also included.

WARNING

The card gives your physicians, dentists and nurses valuable information that is necessary if you should need to undergo any special diagnostic testing such as magnetic resonance imaging (MRI) or magnetic resonance angiography (MRA). Please refer to the Express SD Directions for Use for additional information. There are also phone numbers on the card that your physicians can call if they have any questions. If the information within the stent implant card has not been completed prior to your discharge from the hospital, please contact the implanting physician for this information.

Patient Name	Patient Phone Number
Implanting Physician's Name	Stent Material
Physician's Phone Number	Date of Implant
PLEASE CARRY YOUR CARD AT ALL TIMES. Before you have a Magnetic Resonance Imaging (MRI) scan, or for questions regarding your Stent System or procedure, please contact the implanting physician.	
Stent Identification Information	
Product Name	Product Name
Product Code	Product Code
Product Lot Number	Product Lot Number
Stent Location	Stent Location
Stent Identification Information	
Product Name	Product Name
Product Code	Product Code
Product Lot Number	Product Lot Number
Stent Location	Stent Location

Risks and benefits

The implantation of stents in blood vessels throughout the body is routinely performed to treat blockages and to attempt to prevent re-narrowing.

As with any stent procedure, there is a possibility that complications may occur, including, but not limited to, the following:

- Air bubble(s) in your artery
- Allergic reactions
- Bleeding
- Blood clot(s)
- Bruising or leakage of blood at your groin area or catheter insertion site
- Death
- Heart attack
- Infection
- Injury or damage to your artery or wall of the artery requiring emergency surgery or potential loss of the kidney
- Migration of the stent from its original placement
- Restenosis or reoccurrence of the artery narrowing around or within the stent
- Renal failure

Your physician and the medical staff will monitor you during and after the procedure for complications. If a complication does occur, your physician will decide if you require treatment and determine what type of therapy you may need.

Risks and benefits continued

The potential benefits of undergoing renal stent placement include improved blood flow to the kidney through the artery being treated. If you had symptoms prior to your procedure, it is possible they may improve or be resolved.

You should not undergo renal artery stent placement if any of the following conditions are present:

- You cannot take medicines that make your blood take longer to clot (anticoagulants).
- You cannot take medicines that make your blood cells slippery and make it more difficult for your blood to clot (antiplatelets).
- You are allergic to stainless steel, chromium or nickel (components of the metal used to make the Express® SD Renal Monorail® Premounted Stent System).

Note: It is very common for your physician to prescribe specific medications before, during and after your stent placement. Common drugs that may be prescribed by your physician include anticoagulants and antiplatelets. These medications are intended to help decrease the risk of forming a blood clot in your artery. Please check with your doctor to find the appropriate medication for you.

Living with renal artery disease

Treatment for renal artery disease includes controlling the factors causing the disease. Some risk factors, such as your age, gender, ethnicity and family history, can't be changed. However, many risk factors for this disease can be modified or reduced.

Your physician may recommend making the following healthy lifestyle changes to help treat the renal artery disease:

- Losing excess weight
- Quitting smoking
- Exercising regularly
- Controlling stress and anger
- Decreasing fat in your diet
- Limiting alcohol consumption

Reducing your risk factors can also have a positive impact on the long-term success of renal artery disease treatment. Talk to your physician today about how to increase your chances for a healthier outcome and a more rewarding life with renal artery disease.

Glossary

Angiographic Suite

A combination x-ray room and operating room where endovascular procedures are performed.

Angioplasty

A minimally invasive treatment of the arteries, to open blocked arterial vessels.

Anticoagulant and Antiplatelet

Medicines that slow down the clotting of blood.

Artery

A blood vessel that carries oxygen-rich blood away from the heart to the rest of the body.

Atherosclerosis

A disease in which the flow of blood is restricted by plaque deposits in the arteries.

Balloon Angioplasty

Opening the blocked artery by using a balloon catheter that is inflated inside the vessel.

Balloon Catheter

A thin tube with a balloon attached to the tip that can be inflated to open blocked arteries.

Blood Vessel

Any of the veins and arteries that carry blood to and from the heart.

Catheter

A relatively long, flexible tube that can be passed through the blood vessels.

Catheterization Lab

A combination x-ray room and operating room where endovascular procedures are performed.

Contrast

X-ray dye used in diagnostic tests.

Endovascular

Relating to a procedure in which a catheter is inserted through the skin into a blood vessel for the treatment of vascular disease.

Femoral Artery

The blood vessels that supply blood to the legs.

Guide Catheter

A small, thin plastic tube used to provide access to parts of the body, such as the renal arteries. A guide catheter provides support for other devices your physician may use during your stenting procedure and helps the devices stay in the right place.

Hypertension

Abnormally high arterial blood pressure.

Minimally Invasive Procedure

A minimally invasive procedure utilizes small

instruments or devices to reduce the size of the insertion site and cause a smaller amount of trauma, like a puncture wound or scar. An invasive procedure requires insertion of an instrument or device into the body through skin or a body orifice for diagnosis or treatment.

MRA (Magnetic Resonance Angiography)

Uses a magnetic field and radio waves to provide pictures of blood vessels inside the body. It is a type of MRI scan.

MRI (Magnetic Resonance Imaging)

A non-invasive method of using a magnetic field and radio waves to produce detailed images of the inside of the human body.

Occlusion

Blockage of blood flow in the artery.

Peripheral

Related to areas of the body outside the heart and brain.

Plaque

An accumulation or buildup of cholesterol, fatty deposits, calcium and collagen in a vessel that leads to blockages.

Renal Arteries

The blood vessels that supply blood to the kidneys.

Renal Artery Bypass

A surgical procedure used to create an alternate route for blood to flow to the kidneys around narrowed or blocked renal arteries.

Renal Artery Endarterectomy

A surgical procedure that removes atherosclerotic plaque from the walls of the renal arteries.

Restenosis

Re-narrowing of the artery after treatment.

Sedative

A type of medication that makes you relaxed and sleepy. Also called sedation.

Stenosis

A narrowing of the artery.

Stent

An expandable metal tube that supports the blood vessel wall and maintains blood flow through the opened vessel.

Vascular Closure Device

Used to close the puncture site in an artery after a minimally invasive procedure.

For more information about indications, contraindications, warnings and instructions for the Express® SD Renal Monorail® Premounted Stent System, visit **www.bostonscientific.com**. You can also call Boston Scientific customer service at **1.888.272.1001** to request copies of the Directions for Use (DFU).

CAUTION: Federal (USA) law restricts these products to sale by or on the order of a physician.

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